REMARKS

Formal Matters

Claims 29-30, 36-40, 46-49, 52-54 are currently pending in this application. Claims 1-28, 31-35, 41-45 and 50-51 were previously canceled.

35 U.S.C. § 103(a)

The Office Action maintains the rejection of claims 29, 30, 36-40, 46-49 and 52-54 under 35 U.S.C. § 103(a) as allegedly being obvious over Motoyama *et al.*, (1998) *Nat. Genet.* 18(2): 104-106 in view of U.S. Patent No. 5,932,448 to Tso *et al.* ("Tso").

The Office Action concedes that Motoyama does not disclose a human patched-2 polypeptide or even a patched-2 polypeptide having the percent identity as the claimed patched-2 polypeptide. Furthermore, the Office Action concedes that Motoyama does not teach antibodies against any patched-2 polypeptide.

The Office Action applies Tso for teaching "general methods for producing bispecific antibodies" including the use of monoclonal antibodies in producing bispecific antibodies. The Office Action concedes that Tso does not teach or suggest monoclonal antibodies against a patched-2 polypeptide.

Nevertheless, the Office Action makes a hypothetical combination of Motoyama and Tso stating that one of skill in the art would be motivated to make anti-patched-2 antibodies against the polypeptide disclosed in Motoyama using the techniques disclosed in Tso and that such antibodies "would inherently bind specifically to the human patched-2 polypeptide of SEQ ID NO:2, absent evidence to the contrary." Applicants disagree.

To meet the burden of a *prima facie* case of inherency, the Examiner must provide "a basis of fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic <u>necessarily</u> flows from the teachings of the applied prior art." (MPEP 2112) (emphasis in original). "Mere possibilities or even probabilities are not enough to

establish inherency." (*See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

"The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient."

(*In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations

omitted)). The result must flow inevitably and always.

> Further, since a basis in fact and technical reasoning is required when
> inherency is invoked, a failure to provide such evidence or rationale is
> fatal to the reliance on this doctrine. This is only logical since
> evidence "must make clear" that the allegedly inherent subject matter
> is necessarily present in (i.e., necessarily flows from) the disclosure of
> cited art.
> (*MPEP* 2112).

The Examiner has failed to satisfy the burden of providing a sufficient basis of fact or technical

reasoning to show that a hypothetical monoclonal antibody produced against the mouse protein

that is only "89.3% similar" to the human patched-2 polypeptide would inevitably and always

bind to the human patched-2 protein.

Applicants earnestly submit that claims 29, 30, 36-40, 46-49 and 52-54 distinguish over

Motoyama in view of Tso, and respectfully request withdrawal of the rejection under 35 U.S.C. §

103(a).

SUMMARY

Claims 29, 30, 36-40, 46, 49 and 52-54 are pending in the application. Applicants respectfully request reconsideration and allowance of the claims.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is strongly encouraged to call the undersigned at the number indicated below.

This response is submitted with a Petition for a two-month extension of time and requisite fee. However, in the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Applicants respectfully request allowance of the claims as presented herein.

Respectfully submitted,

GENENTECH, INC.

Date: ___August 3, 2009___   By: _____/Patrick J. Farley/____

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